

REMARKS/ARGUMENTS

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Claims 1 - 17 are presented for examination.

The specification is objected to under the first paragraph of 35 USC 112. Applicants request reconsideration.

1) The Examiner cites as basis for this objection, Applicants' use of the phrase "progestogen equivalent". Applicants respond that in the case of the claimed subject matter, this term is not capable of as broad an interpretation as the Examiner sets forth. All claims are limited to the progestogen being a) desogestrel and b) administered at a daily dose between 0.05 to 1.0 mg/day. This limitation is stated in claims 1, 10 and 17 in the last three lines of each claim. Given this limited claim scope, the Examiner's discussion of the "number of "progestogen equivalent" compounds" inconsequential. Considering desogestrel limited claims within the dosage limitations given, "undue experimentation" regarding the progestogen is respectfully unwarranted.

2) The Examiner cites as basis for this objection, Applicants' use of the phrase "estrogen equivalent". Applicants respond that the phrase is not capable of as broad an interpretation as asserted. First, as a practical matter, there are a very limited number of preferred estrogens. Secondly, the range of the estrogen equivalent dose is quite narrow and easily bench marked against a very common daily dose of ethinyl estradiol which is 35 micrograms/day. Reconsideration is requested. In view of the above, the Examiner is particularly requested to consider the adequacy of the specification in view of claims limited as in claims 4 - 7 or 12 - 15. Isolating this aspect of the objection, these claims should address the issues raised by the Examiner.

3) In regard to this objection generally, the claim scope is not of such breadth that undue experimentation is a substantial issue. The claimed subject matter is a 21 day triphasic regime, of increasing progestogen dose, of constant estrogen dose, where the progestogen is desogestrel within a stated range, and where the estrogen is within a narrow specific range.

Claims 1 - 15 and 17 are rejected under 35 USC 112, first paragraph. Reconsideration is requested.

The bases for reconsideration are set forth above in connection with the objection to the specification. Given the Examiner's view of claim 16, Applicants request particular consideration of claim 8.

Claims 1 - 15 and 17 are rejected under 35 USC 112, second paragraph. Reconsideration is requested.

The Examiner's discussion of this rejection is consistent with the reasoning provided in connection with the objection to the specification. Thus, Applicants again refer to their response as given above. Again, Applicants request specific reconsideration of claim 8.

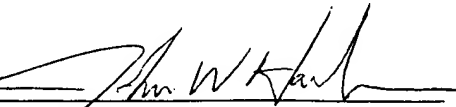
Claims 1 - 17 are rejected under 35 USC 103 as obvious in view of Pasquale (839) and Darney, et al. of record. Applicants request reconsideration.

Applicants have found unexpectedly good cycle control in low dose estrogen, triphasic regimens of the type claimed herein and in the parent application now issued as US Pat. No. 6214815. Critically, Applicants assert that the claimed estrogen dose in combination with the triphasic administration of progestogen results in exceptional bleeding control for a low dose estrogen product. Applicants concede that altering estrogen and/or progestogen doses in general might be expected to alleviate irregular bleeding in women. However, it is generally accepted as well that good cycle control can best be obtained by increasing the

doses of these medicaments. Applicants invention focuses on obtaining good cycle control in contraceptive regimens that are considered low dose estrogen regimens. Applicants request reconsideration.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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